SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name or designation of the mixture	LAMICTAL TABLETS
Registration number	-
Synonyms	LAMICTAL TABLET 25MG * LAMICTAL TABLET 50MG * LAMICTAL TABLET 100MG * LAMICTAL TABLET 150MG * LAMICTAL TABLET 200MG * LAMICTAL VALPROATE STARTER PACK 25MG * LAMICTAL MONOTHERAPY STARTER PACK 25MG * LAMICTAL NON-VALPROATE STARTER PACK 50MG * LAMICTAL COMPRIMES * LAMICTAL COMPRIMIDOS * LAMICTIN TABLETS * LAMOTRIGINE, FORMULATED PRODUCT
Issue date	24-May-2018
Version number	13
Revision date	07-May-2021
Supersedes date	24-May-2018

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses	Medicinal Product. This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.
Uses advised against	No other uses are advised.

1.3. Details of the supplier of the safety data sheet

Company name	GlaxoSmithKline UK
Address:	980 Great West Road Brentford, Middlesex TW8 9GS UK
Telephone:	+44-20-8047-5000 (General Inquiries)
Email:	msds@gsk.com
Website:	www.gsk.com

EMERGENCY CONTACTS

	VERISK 3E GLOBAL INCIDENT RESPONSE
Telephone:	+(44) 20 35147487 or 0 800 680 0425 (In country) +(1) 760 476 3961 (International) 24/7; multi-language response
Contract Number:	334878

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

Classification according to Regulation (EC) No 1272/2008 as amended

Health hazards

Acute toxicity, oral	Category 4	H302 - Harmful if swallowed.

Hazard summary Harmful if swallowed. Caution - Pharmaceutical agent. See section 11 of the SDS for additional information on health hazards.

2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

Contains: INDIGO CARMINE, LAMOTRIGINE, MAGNESIUM STEARATE, MICROCRYSTALLINE CELLULOSE, Polyvinylpyrrolidone

Hazard pictograms

Signal word Warning

Hazard statements

H302 Harmful if swallowed.

Precautionary statements

Prevention

P264 Wash thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

Response

P330 Rinse mouth.

Storage Not available.

Disposal

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Supplemental label information 31 % of the mixture consists of component(s) of unknown acute oral toxicity. 100 % of the mixture consists of component(s) of unknown acute dermal toxicity. 68.2 % of the mixture consists of component(s) of unknown acute hazards to the aquatic environment. 65.1 % of the mixture consists of component(s) of unknown long-term hazards to the aquatic environment.

2.3. Other hazards Caution - Pharmaceutical agent. See section 11 of the SDS for additional information on health hazards.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	Index No.	Notes
LAMOTRIGINE	31 - 50	84057-84-1 281-901-8	-	-	
Classification: Acute Tox. 3;H301;(ATE: 205 mg/kg)					
MICROCRYSTALLINE CELLULOSE	14 - 31	9004-34-6 232-674-9	-	-	
Classification: -					
Polyvinylpyrrolidone	3 - 5	9003-39-8 -	-	-	
Classification: Aquatic Chronic 3;H412					
MAGNESIUM STEARATE	≤ 1	557-04-0 209-150-3	-	-	
Classification: -					
INDIGO CARMINE	0.16	860-22-0 212-728-8	-	-	
Classification: Acute Tox. 4;H302;(ATE: 500 mg/kg), Resp. Sens. 1;H334, Skin Sens. 1;H317, Muta. 2;H341					
Other components below reportable levels	15 - < 35				

List of abbreviations and symbols that may be used above

#: This substance has been assigned Union workplace exposure limit(s).
M: M-factor
PBT: persistent, bioaccumulative and toxic substance.
vPvB: very persistent and very bioaccumulative substance.
All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

Composition comments The full text for all H-statements is displayed in section 16.

SECTION 4: First aid measures

General information IF exposed or concerned: Get medical advice/attention. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance.

4.1. Description of first aid measures

Inhalation If exposed to excessive levels of dusts or fumes, remove to fresh air and get medical attention if cough or other symptoms develop. Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist.

Skin contact	Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if irritation develops and persists.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	If swallowed: immediately call a poison centre or doctor/physician. Rinse mouth. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.
4.2. Most important symptoms and effects, both acute and delayed	Symptoms of overexposure may be headache, dizziness, tiredness, nausea and vomiting. The following adverse effects have been noted with therapeutic use of this material: somnolence; insomnia; tremor; blurred vision; back pain; symptoms of hypersensitivity (such as skin rash, hives, itching); incoordination; gastrointestinal distress; depression. Diarrhoea. Unconsciousness. Behavioural changes.
4.3. Indication of any immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Keep victim warm. Keep victim under observation. Symptoms may be delayed. No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre.

SECTION 5: Firefighting measures

General fire hazards	No unusual fire or explosion hazards noted.
5.1. Extinguishing media	
Suitable extinguishing media	Water. Foam. Dry chemical powder. Carbon dioxide (CO2).
Unsuitable extinguishing media	None known.
5.2. Special hazards arising from the substance or mixture	During fire, gases hazardous to health may be formed.
5.3. Advice for firefighters	
Special protective equipment for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Special fire fighting procedures	Move containers from fire area if you can do so without risk. Use water spray to cool unopened containers.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	Wear appropriate protective equipment and clothing during clean-up.
For emergency responders	Keep unnecessary personnel away. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.
6.2. Environmental precautions	Avoid discharge into drains, water courses or onto the ground.
6.3. Methods and material for containment and cleaning up	Large Spills: Stop the flow of material, if this is without risk. Following product recovery, flush area with water. Small Spills: Clean surface thoroughly to remove residual contamination. Never return spills to original containers for re-use.
6.4. Reference to other sections	For personal protection, see section 8 of the SDS. For waste disposal, see section 13 of the SDS.

SECTION 7: Handling and storage

7.1. Precautions for safe handling	Avoid prolonged exposure. When using, do not eat, drink or smoke. Provide adequate ventilation. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Observe good industrial hygiene practices.
7.2. Conditions for safe storage, including any incompatibilities	Store in tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).
7.3. Specific end use(s)	Medicinal Product

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

GSK

Components	Type	Value	Form
LAMOTRIGINE (CAS 84057-84-1)	8 HR TWA	250 mcg/m3	Skin
	OHC	2	Skin

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value	Form
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	STEL	20 mg/m3	Inhalable dust.
	TWA	4 mg/m3	Respirable dust.
		10 mg/m3	Inhalable dust.

Biological limit values No biological exposure limits noted for the ingredient(s).

Recommended monitoring procedures Follow standard monitoring procedures.

Derived no effect levels (DNELs) Not available.

Predicted no effect concentrations (PNECs) Not available.

Exposure guidelines

8.2. Exposure controls

Appropriate engineering controls Ventilate as needed to control airborne dust. Use explosion-proof ventilation equipment if airborne dust levels are high. Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. If engineering measures are not sufficient to maintain concentrations of dust particulates below the OEL (occupational exposure limit), suitable respiratory protection must be worn.

Individual protection measures, such as personal protective equipment

General information Follow all local regulations if personal protective equipment (PPE) is used in the workplace.

Eye/face protection Not normally needed. If contact is likely, safety glasses with side shields are recommended.

Skin protection

- Hand protection Not normally needed. For prolonged or repeated skin contact use suitable protective gloves. With respect to the above precautions select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).

- Other Not normally needed. Wear suitable protective clothing as protection against splashing or contamination.

Respiratory protection No personal respiratory protective equipment normally required. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. Where breathable aerosols/dust are formed, use suitable combination filter for gases/vapours of organic, inorganic, acid inorganic, alkaline compounds and toxic particles (eg. EN 14387).

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

Hygiene measures Keep away from food and drink. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

Environmental exposure controls

Hazard guidance and control recommendations Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. Fume scrubbers, filters or engineering modifications to the process equipment may be necessary to reduce emissions to acceptable levels.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state Solid.

Form Tablet.

Colour Not available.

Odour	Not available.
Melting point/freezing point	Not available.
Boiling point or initial boiling point and boiling range	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Flash point	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
pH	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	Not available.
Particle characteristics	Not available.
Other safety characteristics	
Explosive properties	Not explosive.
Oxidising properties	Not oxidising.

SECTION 10: Stability and reactivity

10.1. Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
10.2. Chemical stability	Material is stable under normal conditions.
10.3. Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
10.4. Conditions to avoid	Contact with incompatible materials.
10.5. Incompatible materials	Strong oxidising agents. Fluorine.
10.6. Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition. No hazardous decomposition products are known.

SECTION 11: Toxicological information

General information	Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.
Information on likely routes of exposure	
Inhalation	Health injuries are not known or expected under normal use. Prolonged inhalation may be harmful.
Skin contact	No adverse effects due to skin contact are expected.
Eye contact	Direct contact with eyes may cause temporary irritation.
Ingestion	Health injuries are not known or expected under normal use. Harmful if swallowed.
Symptoms	Symptoms of overexposure may be headache, dizziness, tiredness, nausea and vomiting. The following adverse effects have been noted with therapeutic use of this material: somnolence; insomnia; tremor; blurred vision; back pain; symptoms of hypersensitivity (such as skin rash, hives, itching); incoordination; gastrointestinal distress; depression. Behavioural changes. Diarrhoea. Unconsciousness.

11.1. Information on toxicological effects

Acute toxicity	Health injuries are not known or expected under normal use. Harmful if swallowed.

Components	Species	Test Results
LAMOTRIGINE (CAS 84057-84-1)		
Acute		
Oral		
LD50	Mouse	245 mg/kg

Components	Species	Test Results
	Rat	205 mg/kg
Chronic		
Oral		
LOEL	Monkey	5 mg/kg/day, 1 years
Subacute		
Oral		
LD	Rat	50 mg/kg/day, 30 day
LOEL	Monkey	10 mg/kg/day, 30 day Behavioural effects.
	Rat	10 mg/kg/day, 30 day Rat-specific kidney effects.
Subchronic		
Oral		
LD	Monkey	20 mg/kg/day, 6 months Convulsive effects, Death.
	Rat	25 mg/kg/day, 6 months
LOEL	Rat	1 mg/kg/day, 6 months Rat-specific kidney effects.
NOAEL	Monkey	5 mg/kg/day, 90 day
NOEL	Monkey	10 mg/kg/day, 6 months
TD	Monkey	10 mg/kg/day, 90 day Behavioural effects.
MAGNESIUM STEARATE (CAS 557-04-0)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)		
Acute		
Dermal		
LD50	Rabbit	> 2000 mg/kg
Oral		
LD50	Rat	> 2000 mg/kg
Polyvinylpyrrolidone (CAS 9003-39-8)		
Acute		
Oral		
LD50	Rat	> 5000 mg/kg

Skin corrosion/irritation No adverse effects due to skin contact are expected.

Corrosivity

LAMOTRIGINE	OECD 404 Result: Non-irritant Species: Rabbit

Irritation Corrosion - Skin: P.I.I. value

LAMOTRIGINE	0
MAGNESIUM STEARATE	0

Serious eye damage/eye irritation Direct contact with eyes may cause temporary irritation.

Eye

LAMOTRIGINE	OECD 405 Result: Mild irritant Species: Rabbit

Eye / Kay and Calandra class - Intact

LAMOTRIGINE	3
MAGNESIUM STEARATE	4 Recovery Period: 2 days

Respiratory sensitisation Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin sensitisation This product is not expected to cause skin sensitisation.

Sensitisation

LAMOTRIGINE	SAR / QSAR, DEREK, Lhasa, UK Result: Negative

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic. Health injuries are not known or expected under normal use.

Mutagenicity

LAMOTRIGINE	<= 200 mg/kg/day Micronucleus Test Result: Negative Species: Rat Ames Result: Negative BlueScreen mammalian cell mutation assay Result: Negative GreenScreen mammalian cell mutation assay Result: Negative In vitro cytogenetic Assay Result: Negative L5178Y mouse lymphoma thymidine kinase locus assay Result: Negative

Carcinogenicity No data available to indicate product or any components present at greater than 0.1% are carcinogenic. Carcinogenic effects are not expected as a result of occupational exposure.

LAMOTRIGINE	10 - 15 mg/kg/day Result: Negative Species: Rat 10 - 30 mg/kg/day Result: Negative Species: Mouse

IARC Monographs. Overall Evaluation of Carcinogenicity

Polyvinylpyrrolidone (CAS 9003-39-8)	3 Not classifiable as to carcinogenicity to humans.

Reproductive toxicity This product is not expected to cause reproductive or developmental effects.

Reproductivity

LAMOTRIGINE	12.5 - 25 mg/kg/day Embryofetal Development Result: Maternal toxicity; adverse foetal effects Species: Rat 20 mg/kg/day Fertility Result: Parental toxicity, no adverse effects on fertility. Species: Rat 5 - 20 mg/kg/day Pre- and Post-natal development Result: Maternal toxicity; adverse foetal effects Species: Rat 5 - 30 mg/kg/day Embryofetal Development Result: Maternal toxicity; Foetal NOAEL Species: Rabbit 6.25 mg/kg/day Embryofetal Development Result: Maternal toxicity; Foetal NOAEL Species: Rat Breast feeding, Possible transient drug-induced effects in breast-fed infants. Species: Human

Specific target organ toxicity - single exposure Not assigned. Based on available data, the classification criteria are not met.

Specific target organ toxicity - repeated exposure Not assigned. Based on available data, the classification criteria are not met.

Aspiration hazard Not an aspiration hazard.

Mixture versus substance information No information available.

11.2. Information on other hazards

Endocrine disrupting properties Not available.

Other information Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.

SECTION 12: Ecological information

12.1. Toxicity Contains a substance which causes risk of hazardous effects to the environment.

Components		Species	Test Results
LAMOTRIGINE (CAS 84057-84-1)			
Aquatic			
Acute			
Activated Sludge Respiration	IC50	Residential sludge	> 1000 mg/l, 3 hours
Algae	EC50	Green algae (Selenastrum capricornutum)	39.7 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	56 mg/l, 48 hours
	NOEC	Water flea (Daphnia magna)	30 mg/l, 48 hours
Fish	LC50	Rainbow trout (Adult Oncorhyncus mykiss)	85 mg/l, 96 hours
	NOEC	Rainbow trout (Adult Oncorhyncus mykiss)	60 mg/l, 96 hours
Microtox	MIC	Aspergillus flavus	> 185 mg/l
		Azotobacter chroococcum	> 185 mg/l
		Nostoc sp.	> 185 mg/l
Other	MIC	Pseudomonas acidovorans	> 185 mg/l
Chronic			
Algae	NOEC	Green algae (Selenastrum capricornutum)	7.5 mg/l, 72 hours
Crustacea	LOEC	Ceriodaphnia dubia	> 10 mg/l, 7 days
	NOEC	Ceriodaphnia dubia	10 mg/l, 7 days
MAGNESIUM STEARATE (CAS 557-04-0)			
Aquatic			
Acute			
Fish	EC50	Orange-red killfish (Adult Oryzias latipes)	130 mg/l, 96 hours
Polyvinylpyrrolidone (CAS 9003-39-8)			
Acute			
	IC50	Activated sludge	> 1000 mg/l, 3 hours Static test
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	84 mg/l, 48 hours Static test
	NOEC	Water flea (Daphnia magna)	32 mg/l, 48 hours Static test

12.2. Persistence and degradability No data is available on the degradability of this product.

Photolysis

Half-Life (Photolysis-Atmospheric)

MAGNESIUM STEARATE	17 Hours Estimated

UV/visible spectrum wavelength

LAMOTRIGINE	300 nm Measured, pH >6
MAGNESIUM STEARATE	210 nm

Hydrolysis

Half-Life (Hydrolysis-Neutral)

LAMOTRIGINE	> 1 years Measured

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

LAMOTRIGINE	0 %, 14 days Modified Zahn-Wellens, Activated sludge
MAGNESIUM STEARATE	77 %, 28 days BOD
Polyvinylpyrrolidone	0 %, 28 days Modified MITI test, Activated sludge

Percent Degradation (Aerobic Biodegradation-Ready)

LAMOTRIGINE	0 %, 28 days Modified Sturm test.
MAGNESIUM STEARATE	95 %, 22 days Sturm test

Percent Degradation (Aerobic Biodegradation-Soil)

MAGNESIUM STEARATE	50 %, 13 days

12.3. Bioaccumulative potential No data available for this product.

Partition coefficient n-octanol/water (log Kow)

LAMOTRIGINE	1.4 (Measured).

Bioconcentration factor (BCF)

MAGNESIUM STEARATE	> 9999 Estimated

12.4. Mobility in soil No data available.

Adsorption

Sludge/Biomass Distribution Coefficient - Log Kd

LAMOTRIGINE	1.15 Measured, pH 7

Soil/Sediment Sorption - Log Koc

MAGNESIUM STEARATE	5.86 Estimated

Mobility in general

Volatility

Henry's law

LAMOTRIGINE	0 atm m^3/mol, 25 C Estimated

Distribution

Octanol/water distribution coefficient log DOW

LAMOTRIGINE	1.4, pH 7 1.4, pH 9

12.5. Results of PBT and vPvB assessment Not available.

12.6. Endocrine disrupting properties Not available.

12.7. Other adverse effects Not available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Residual waste	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.
EU waste code	The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Disposal methods/information	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not discharge into drains, water courses or onto the ground. Dispose of contents/container in accordance with local/regional/national/international regulations.
Special precautions	Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

ADR

14.1. UN number	Not available.
14.2. UN proper shipping name	Not available.
14.3. Transport hazard class(es)	
Class	Not available.
Subsidiary risk	-
Hazard No. (ADR)	Not available.
Tunnel code	Not available.
14.4. Packing group	Not available.
14.5. Environmental hazards	No.
14.6. Special precautions for user	Not available.

IATA

14.1. UN number	Not available.
14.2. UN proper shipping name	Not available.
14.3. Transport hazard class(es)	Not available.
Subsidiary class(es)	-
14.4. Packing group	Not available.
Labels required	Not available.
14.5. Environmental hazards	No.

14.6. Special precautions for user	Not available.

IMDG

14.1. UN number	Not available.
14.2. UN proper shipping name	Not available.
14.3. Transport hazard class(es)	
Class	Not available.
Subsidiary risk	-
14.4. Packing group	Not available.
14.5. Environmental hazards	
Marine pollutant	No.
EmS	Not available.
14.6. Special precautions for user	Not available.

Read safety instructions, SDS and emergency procedures before handling.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I and II, as amended

Not listed.

Regulation (EU) 2019/1021 On persistent organic pollutants (recast), as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 1 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 2 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 3 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex V as amended

Not listed.

Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry, as amended

Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(10) Candidate List as currently published by ECHA

Not listed.

Authorisations

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended

Not listed.

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended

Not listed.

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work, as amended.

Not listed.

Other EU regulations

Directive 2012/18/EU on major accident hazards involving dangerous substances, as amended

Not listed.

Other regulations	The product is classified and labelled in accordance with Regulation (EC) 1272/2008 (CLP Regulation) as amended. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006, as amended.
National regulations	Follow national regulation for work with chemical agents in accordance with Directive 98/24/EC, as amended.
15.2. Chemical safety assessment	No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations

ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways.
ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.
CAS: Chemical Abstract Service.
CEN: European Committee for Standardization.
IATA: International Air Transport Association.
IBC Code: International Code for the Construction and Equipment of Ships Carrying Dangerous Chemicals in Bulk.
IMDG: International Maritime Dangerous Goods.
MARPOL: International Convention for the Prevention of Pollution from Ships.
PBT: Persistent, bioaccumulative and toxic.
RID: Regulations concerning the International Carriage of Dangerous Goods by Rail.
STEL: Short term exposure limit.
TWA: Time Weighted Average.
vPvB: Very persistent and very bioaccumulative.

References

GSK Hazard Determination

Information on evaluation method leading to the classification of mixture

The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.

Full text of any H-statements not written out in full under Sections 2 to 15

H301 Toxic if swallowed.
H302 Harmful if swallowed.
H317 May cause an allergic skin reaction.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H341 Suspected of causing genetic defects.
H412 Harmful to aquatic life with long lasting effects.

Revision information

This document has undergone significant changes and should be reviewed in its entirety.

Training information

Follow training instructions when handling this material.

Disclaimer

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.